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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,306	04/02/1999	THOMAS GINGERAS	018547-01857	3558
33522	7590	12/03/2003	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE, N.W. WASHINGTON, DC 20004			SIEW, JEFFREY	
			ART UNIT	PAPER NUMBER

1637

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/285,306	GINGERAS ET AL.	
	Examiner	Art Unit	
	Jeffrey Siew	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-10 is/are allowed.
- 6) ☒ Claim(s) 11-15 is/are rejected.
- 7) ☐ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. On page 8 line 18 the URL should be deleted. While in the advisory action of 5/31/02 stated that the proposed amendment would overcome the objection to the specification, upon further review and study of the MPEP 608.1, the objection is maintained.

MPEP 608.01 states

.....Examiners must review patent applications to make certain that hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not included in a patent application. Examples of a hyperlink or a browser-executable code are a URL placed between these symbols "<>" and http:// followed by a URL address. When a patent application with embedded hyperlinks and/or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via **a web browser, the URL is interpreted as a valid HTML code** and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial website. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites.

If hyperlinks and/or other forms of browser-executable code are embedded in the text of the patent application, **examiners should object to the specification** and indicate to applicants that the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion....

The amendment filed 8/25/03 to the specification inserts www.ncbi.nlm.nih.gov where a dot is introduced before "gov". The preceding portion would still be recognized as a hyperlink. It is believed that the URL designation still would be interpreted as valid HTML code and would become a live web link if it existed. USPTO policy does not permit the USPTO to link to any

commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. The objection is therefore maintained. The deletion of the complete phrase is required.

2. The status of all referenced US applications must be updated. (see particularly first page).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Based on the art that was published after applicant's filing date, the prior art has disclosed a full sequence of rpoB gene of *M. tuberculosis* which was revealed to extend 3,534 base pairs (see Miller et al Antimicrob Agents chemotherapy April 1994 pp. 805-811). There is expected variation among the species of DNA which encode the mycobacterial rpoB gene. SEQ ID Nos 2 -10 are of the sizes 626 or 705bp and each sequence as being indicative of *M. avium* strain (see Table 2). The gene then would have many interspecific and intraspecific differences that would lie within and outside the claimed fragments. The specification has only disclosed

only fragments that may be used to distinguish M. avium strain from other strains but does not provide support for all variations of the gene that lie outside the fragment. The nature of the variants is that they are variant structures where the structure and function of one does not necessarily provide guidance to the structure and function of others. The disclosure of M. avium rpoB fragments do not provide the guidance of the structure and function of the complete gene within the M. avium strain and in other strains. The common attributes of the genus, other than SEQ ID Nos 2-10, are not described. Moreover, the lower limit of 100 bases within 3533 base gene would not provide sufficient written description to the wide number of base variations of the varying species that not only lie outside 100 bases as well as the disclosed SEQ ID Nos. The specification would not provide adequate written support for such a claim. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only a few fragments of a very diverse genus is not representative of the variants of the genus and is insufficient to support the claim.

The response filed 8/25/03 has been fully considered and deemed not persuasive. The response states that according to the advisory action the proposed amendment would overcome the 112 first paragraph rejection. An amendment does not appear to have been incorporated. The claim still incorporates the term "consisting of" and has added the term "about" and also still includes at least. In addition to the 112 second paragraph issues these phrases cumulatively would raise, the claims are not limited solely to the SEQ ID No;s but would still encompass a larger scope that originally raised the cited 112 first paragraph written description rejection. The response further argues that the claim language cannot be interpreted to include variations that lie outside of the fragment consisting of at least about 100 contiguous bases. The language has

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essentially reopened the closed language thus leading to reasonable reading on sequence outside the 100 bases. The rejection is maintained over claim 1.

Claim Rejections - 35 USC § 102

4 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by De Beenhouwer et al (WO 95/33851 14 December 1995).

De Beenhouwer et al teach a method of simultaneous detection of the antibiotic resistance and identification mycobacterium species (see whole doc.). They teach that isolating and concentrating polynucleic acids in sample, amplify *rpoB* gene and hybridize with *rpoB* probes to differentiate several non-*M. tuberculosis* isolates (see abstract & claim 1). They teach *M. avium* 5887 *rpoB* sequence of 324 bp contiguous length which contains 72 contiguous base pairs (bp252-324) that are complementary to claimed SEQ ID No. 10 (bp219-291) which contains the highlighted bp 245, 251 & 257. They teach a sequence of *M. paratuberculosis* strain 316F *rpoB* which contains 67 contiguous base pairs (bp 252-319) that are 100% complementary to SEQ. ID NO. 8 (bp201-268) (see Figure 6 & claim 13) which contains highlighted base pair 218. They then teach that these non Tuberculosis sequences were sequenced and compared to

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rpoB gene sequence of M. tuberculosis in order to develop probes which differentiate M. tuberculosis from other species (see page 30-31)

The response filed 8/25/03 has been fully considered and deemed not persuasive. The response argues that under the stringent conditions recited in the claim De Beenhouwer probes would not bind to the recited sequences. The temperature of the conditions equate to room temperature. It would be expected the De Beenhouwer probes would meet the limitation particularly when De Beenhouwer et al used the probes to differentiate M. tuberculosis from other species. The rejection is maintained.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The phrase “consisting of at least about” renders claim 1 indefinite. It is unclear as to what the range of the scope of the probe length. Although consisting of has been determined to be closed language. In combination with “at least about” contravenes the established meaning of “consisting of” by reopening the closed language. Deletion “of at least about” would overcome the rejection.

SUMMARY

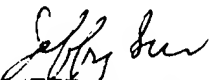
6. Claims 2-10 are allowable. Claim 16 is objected to for depending on a rejected claim. There is no prior art that teach or suggest a probe consisting of SEQ ID NO: 2-10 or a method of classifying mycobacteria by comparing the complete sequence of at least one sequence sequences selected from SEQ ID NO:2-10. Concerning claim 16 there is no prior art that teach the recited probe of at least 100 contiguous bases. The closest prior art is De Beenhouwer et al who teach fragments less than 100 base pairs complementary to SEQ ID NO:7. Claim 1 is rejected under 112 first and second paragraph and would be free of the prior art if amended to only recite "consisting of."

CONCLUSION

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number before January 22, 2003 is (703) 305-3886 and thereafter can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.


JEFFREY SIEW
PRIMARY EXAMINER

November 30, 2003